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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DALE B. SCHENK

Appeal 2010-004495
Application 10/777,792
Technology Center 1600

Before ERIC GRIMES, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges.*

WALSH, *Administrative Patent Judge.*

DECISION ON REQUEST FOR RECONSIDERATION[1]

Dale B. Schenk (Appellant) requests reconsideration of the Decision on Appeal mailed August 30, 2010, which affirmed obviousness rejections of all the pending claims.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

ANALYSIS

The background of this request is, briefly, that Appellant claims a composition comprising the first seven amino acids of the known β amyloid peptide (aka Aβ), linked to a toxoid. The Examiner concluded that the composition would have been obvious because Selkoe taught making antibodies against Aβ by using a peptide of about 8 amino acids as the antigen, Wong taught linking the first ten amino acids of Aβ as an antigen to a carrier to increase antibody production against Aβ, and Penney taught using a toxoid as a carrier for antigens. We affirmed.

The first ground for reconsideration concerns the meaning of Selkoe's teaching to use an Aβ fragment of "about 8 or more residues." (Req. Reh'g[2] 2-3.) The Decision agreed with the Examiner's interpretation that "about 8" included 7. (Dec. 7, citing Ans. 3.)

Appellant views "about 8" as a teaching that "the minimum length cannot be defined with absolute certainty," and "suggest[s] there is some risk of failure in an Aβ1-7 fragment or a need to expend more effort to generate a suitable antibody." (Req. Reh'g 2.) According to Appellant, "the claimed invention involves the additional complexity presented by a possible risk of failure or additional effort without any compensating advantages," and "no or insufficient reason has been provided for specific selection of an Aβ1-7 fragment rather than Aβ1-10 or many other possible alternative Aβ fragments whose lengths would not present any concerns with respect to generating a suitable antibody." (*Id.* at 3.)

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[2] Citations are to Appellant's "Corrected Request For Rehearing Under 37 C.F.R. 41.50(b)(2)" filed with a Communication dated Nov. 12, 2010.

We are not persuaded that these arguments establish a ground for reversal. Selkoe's teaching that "about 8" Aβ amino acids are sufficient is presumed enabled. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003) (a patent's disclosure is presumed enabled). Further, "[o]bviousness does not require absolute predictability. Only a reasonable expectation that the beneficial result will be achieved is necessary to show obviousness." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (citations omitted). Appellant's vague references to "added features or steps" (Req. Reh'g 3) are not evidence that actual features or steps beyond those described in the references would have been needed. Similarly, Appellant's "assumption of unnecessary complications" (*id.*), is not evidence that a person having ordinary skill in the art could not have combined the Selkoe, Wong, and Penney teachings with a reasonable expectation of success.

Appellant's second point is that there is "evidence that the Aβ1-7 moiety of the claimed conjugate has an unexpected advantage relative to the Aβ1-10 fragment used by Selkoe." (*Id.*) According to Appellant,

> [i]n the aggregate, these reports provide evidence that an Aβ1-7 fragment is likely to be equally effective as an Aβ1-10 fragment in inducing three classes of antibodies primarily responsible for plaque clearing but even less likely to have T-cell mediated side effects because of its smaller size relative to the approximate minimum size of T-cell epitopes reported by Rammensee.

(*Id.* at 4.)

The "evidence" consists of hypotheses, not results obtained from using the claimed conjugates. Appellant agrees that the "evidence" is actually an inference based on combining information in the art, in the

Specification, and in post-filing date publications: "Appellant has never contended that the underlying evidence was generated using a conjugate as claimed. Nevertheless, the evidence inferentially supports a conclusion that the Aβ1-7 moiety of the claimed conjugates has an unexpected property of practical importance vis a vis the Aβ1-10 fragment of Selkoe." (*Id.*)

> To reiterate, appellant is not arguing about the advantages of different products, but instead is using the data in the specification defining the location of epitopes responsible for plaque clearing and postfiling data regarding side effects to support an inferential conclusion of unexpected results of practical significance of the Aβ1-7 moiety of the claimed product vis a vis Wong's Aβ1-10 fragment.

(*Id.* at 5.) We do not agree that the inferences constitute evidence of a suitable side-by-side comparison with the closest prior art as is necessary to demonstrate unexpected results.

Appellant argues that the Board overlooked that replacing KLH with a toxoid "confers an unexpected result that the claimed conjugates are rendered more suitable for human therapeutic use." (*Id.* at 7.) The Examiner found that Appellant did not provide evidence to support the assertion (Ans. 9), and we agreed (Decision 9). We did not overlook that argument. When the references relied on explicitly describe a toxoid for improved vaccine compositions for human use, e.g., Penney, col. 2, it was reasonable for the Examiner to require evidence of unexpected results.

Appellant similarly argues that the Board misapprehended the nature of the unexpected result relating to QS-21 (replacing Freund's adjuvant with QS-21) (Req. Reh'g 7), but we are again unpersuaded. The Examiner carefully explained how Hancock disclosed advantages associated with QS-

21 and why QS-21 would have been an obvious choice. (Ans. 5-6.) Appellant recognizes that the art taught the unsuitability of Freund's adjuvant for use in humans, but maintains that "replacing Freund's adjuvant with QS-21 conferred an unexpected result of suitability for human use." (Req. Reh'g 7.) We continue to disagree that the result was unexpected. It is undisputed that Hancock taught QS-21 for use in humans, and its suitability would therefore not have been unexpected.

SUMMARY

We have considered Appellant's request for reconsideration but deny the requested relief.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

DENIED

cdc

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BANK OF AMERICA PLAZA
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CHARLOTTE, NC 28280-4000